

the labeled amount of dextro-amphetamine sulfate and failed to disintegrate in the manner declared on the label; and 502(a)—the label statements "Dextro-Amphetamine Sulfate 15 Mgm. Timed Disintegration Capsule Each Capsule contains 15 mgm. of Dextro-amphetamine sulfate in a special base that provides for time disintegration of the contents throughout a period of about 6-10 hours. This capsule is equivalent to one tablet of 5 mgm. potency taken three times a day" were false and misleading for a product that contained more than 15 mg. of dextro-amphetamine sulfate per capsule and which did not consist of capsules equivalent to those of 5 mg. potency taken three times a day.

DISPOSITION: 11-29-57. Default—destruction.

5474. Soluble saccharin. (F.D.C. No. 40636. S. No. 68-624 M.)

QUANTITY: 1 45-lb. drum at Brooklyn, N.Y.

SHIPPED: From Holland.

LABEL IN PART: "FHT Saccharine Soluble Granular Made in Holland."

LIBELED: 9-12-57, E. Dist. N.Y.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for soluble saccharin set forth in the United States Pharmacopeia since the article exceeded the heavy metals limit of 20 parts per million.

DISPOSITION: 10-18-57. Default—destruction.

5475. Prophylactics. (F.D.C. No. 40576. S. Nos. 44-343/4 M, 44-356/7 M.)

QUANTITY: 27 ctns., each containing 48 pkgs. and each pkg. containing 3 units, at Little Rock, Ark.

SHIPPED: 5-7-57 and 5-27-57, from Atlanta, Ga., by W. H. Reed & Co.

LABEL IN PART: (Pkg.) "Golden Pheasant * * * Prophylactics * * * One Fourth Dozen"; (individual foil wrapped unit) "One Lubricated Golden Pheasant Prophylactic Insist on the Genuine Mfgd. in W. Germany Packed by W. H. Reed & Co., Atlanta, Ga."

RESULTS OF INVESTIGATION: Examination showed that the article was defective in that it contained holes.

LIBELED: 8-22-57, E. Dist. Ark.

CHARGE: 501(c)—the quality of the article fell below that which it purported to possess when shipped; and 502(a)—the label statement "Prophylactics" was false and misleading as applied to a product containing holes.

DISPOSITION: 10-1-57. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

5476. Invertose. (F.D.C. No. 40937, S. No. 78-645 M.)

QUANTITY: 3 ctns., 12 btls. each, at Wichita, Kans.

SHIPPED: Between 3-18-57 and 9-28-57, from Lincoln, Nebr., by Norden Laboratories.

LABEL IN PART: (Btl.) "Norden 500 cc Invertose A source of readily assimilable carbohydrate for parenteral use."

RESULTS OF INVESTIGATION: Examination showed that the article was invert sugar.

*See also Nos. 5464, 5469, 5470, 5473, 5475.

LIBELED: 11-7-57, Dist. Kans.

CHARGE: 502(a)—when shipped, the label of the article contained false and misleading representations that the article was an effective and adequate treatment for milk fever.

DISPOSITION: 12-19-57. Default—destruction.

5477. Cabbex. (F.D.C. No. 40663. S. No. 78-008 M.)

QUANTITY: 29 btls. at Omaha, Nebr., in possession of Vitamin Stores, Inc.

SHIPPED: 4-9-57, from Huntington Park, Calif.

LABEL IN PART: "One Pound Guardian Concentrate Cabbex Cabbage Powder For Cabbage Juice * * * As a supplementary source of the nutrients in cabbage take four teaspoonsful daily."

ACCOMPANYING LABELING: Window placard reading: "Ulcers? Try Cabbex Cabbage Juice Powder \$3.98."

RESULTS OF INVESTIGATION: The article was shipped as described above in 30-lb. bulk drums, and after receipt by the consignee, it was repacked into bottles.

LIBELED: 9-27-57, Dist. Nebr.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an effective treatment for ulcers.

DISPOSITION: 10-25-57. Default—destruction.

5478. Dr. Bronner's Calcium & Phosphorus, Vegetable. (F.D.C. No. 40918. S. Nos. 73-243/4 M.)

QUANTITY: 22 2-oz. btls. and 5 1½-oz. btls. at Denver, Colo.

SHIPPED: Between 1-10-57 and 6-19-57, from Los Angeles, Calif., by Dr. E. H. Bronner & Associates.

LABEL IN PART: "Dr. Bronner's Calcium & Phosphorus, Vegetable made from vegetable calcium, rosehips, rice polish, dulse, barley, yeast & malt."

ACCOMPANYING LABELING: Circular, reading in part, "Dr. Bronner's Calcium & Phosphorus, Vegetable."

LIBELED: 10-30-57, Dist. Colo.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that fluoridation is wrong; that the right way to prevent tooth decay is with organic-vegetable and oceanic calcium food; and that the article was adequate and effective for preventing tooth decay, polio, bone brittleness, and loose dentures.

DISPOSITION: 12-31-57. Default—destruction.

5479. Grapefruit powder. (F.D.C. No. 40523. S. No. 57-929 M.)

QUANTITY: 1 25-lb. tin and a number of 8-oz. jars at Orange City, Fla., in possession of Wolf Laboratories.

SHIPPED: On an unknown date, from Huntington Park, Calif.

LABEL IN PART: (Jar) "Whole Powdered Grapefruit."

RESULTS OF INVESTIGATION: The article in the jars had been repacked from bulk stock which was shipped as described above.

LIBELED: 7-22-57, S. Dist. Fla.